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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,320	05/10/2007	Noriaki Kato	868_012	4731

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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
06/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,320	KATO ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-12,14,18,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-12,14,18,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments, filed June 8, 2010, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 10 – 12, 14 and 18 – 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Mylari (US 6,426,341) in view of Crary (US 5,639,482). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed March 10, 2010 and those set forth below.

6. Claims 10 – 12, 14 and 18 – 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Akita et al. (Acta Med Okayama) in view of Crary (US 5,639,482) and Wani et al. (JK Practitioner 2003). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed March 10, 2010 and those set forth below.

As Applicants do not argue these rejections separately and the arguments mainly focus on the secondary reference used in both rejections so the arguments regarding both rejections are discussed below.

Applicant traverses this rejection on the grounds that there is no chemical relationship between the ARIs shown in the primary references to Mylari and Akita et al. and the selenium-vitamin E combination in Crary and the Examiner has resorted to

hindsight to justify the rejections. These arguments are unpersuasive. While there is no structural similarity for ARIs and the combination of agents used in Crary, structural similarity is not required if the art recognizes that the various compounds have the same activities (e.g., anti-inflammatory compounds contain many different structures but are known in the art to have anti-inflammatory activity). Both ARIs such as SNK-860 and the compounds of Crary are known to decrease diabetic complications. This point is discussed in greater below.

Applicant also argues that there is no reason to expect that SNK-860 would be useful in the treatment of diabetic macular edema. The Examiner has accepted those arguments as evidence by the withdrawal of the prior rejection. These arguments are unpersuasive. The previous rejection was withdrawn based on the declaration stating the diabetic macular edema was a distinct condition from diabetic retinopathy. The Crary reference was cited to show that condition known in the art to be useful for the treatment of diabetic retinopathy are also useful in the treatment of diffuse macular edema in diabetic patients.

In regards to the Crary reference, Applicants argue that Crary merely discloses an efficacy for DME in patients with DR and DME in patients with DME. There is no disclosure of a relationship between efficacy for DR and that for DME. Short term treatment for DME is clearly reported by there is no mention of efficacy for DR. A reference is provided which concludes that therapy evaluation for DR medication needs administration to patients for more than 3 years and Crary also described that the efficacy for DR was achieved by treatment for 3 years. These arguments are

unpersuasive. The prosecution history of this case clearly demonstrates the importance of distinguishing between various ocular complications that arise in diabetic patients. It is unclear whether by "DME" applicant is referring to "diffuse macular edema" or "diabetic macular edema" or is the two terms are being used interchangeably. The instant claims are directed towards treating diabetic macular edema and not towards treating diabetic retinopathy. The arguments are also insufficient to establish the lack of enablement for the claims of the US patent issued to Crary, which are drawn towards the "a method of treating and preventing macular edema of human diabetic retinopathy" (claim 1) or "a method of treating humans susceptible to macular edema of diabetic retinopathy (claims 2 – 4). The invention also aims to "prevent diabetic retinopathy and treat advanced diabetic retinopathy (col 2, ln 51 – 57). Treatment of an aspect of diabetic retinopathy (macular edema of human diabetic retinopathy) is also treatment of diabetic retinopathy (just as normalizing breathing during an asthma attack treats asthma). Clearance of macular edema in diabetic patients was clearly reported by Crary (e.g., col 3, ln 47 – 48). Patient 4 with diffuse macular edema and background diabetic retinopathy was followed for four years and visual acuity was maintained while on the supplementation regimen. Applicants state that DR efficacy was achieved after three years. Thus, the regimen of Crary treats both diabetic retinopathy and diffuse macular edema in diabetic patients and sot eh agents taught are useful in treating both conditions.

Applicant also argues that vitamin E supplements are effective in treating diabetes and ameliorated diabetes mellitus by lowering blood glucose and HbA1c

levels. Amelioration of diabetes by this mechanism leads to amelioration of diabetic complication and is widely accepted by the international community. A person of ordinary skill in the art would not conclude that an agent effective in the treatment of DR is also effective in the treatment of DME. In contrast, SNK-860 does not lower HbA1c levels and is an agent for ameliorating diabetic complications but not for ameliorating diabetes mellitus itself. These arguments are unpersuasive. Crary teaches that agents which decrease complications from diabetes, albeit at an earlier stage in the process by lowering blood glucose levels whose long term levels are reflected by the HbA1c level, prevents or treats macular edema of human diabetic retinopathy. The person of ordinary skill in the art would realize that diabetic patients, based on the disclosure of Crary, with background diabetic retinopathy and/or diffuse macular edema can be treated by a drug which reduces diabetic complications. Diabetic retinopathy is a complication of diabetes mellitus and SNK-860 is effective in the treatment of various complications arising from diabetes (as taught by the primary references). Thus it would obvious to administer SNK-860 to diabetics with diabetic retinopathy alone or with diffuse macular edema to reduce complications arising from diabetes, thus leading to treatment of diabetic macular edema.

Applicants also argue that "[i]t is unequivocal that Crary does not suggest that an agent effective in the treatment of DR is also effective in the treatment of DME" after setting forth a particular fact pattern at the top of page 5 of the response. These arguments are unpersuasive. The fact pattern relies on the 'common technical knowledge in the art' that therapeutic methods of DR and DME are different from each

other. The abstract and text of Crary discusses "a method of treating diabetic retinopathy and a means for preventing its recurrence" (abstract; col 2, ln 51 – 57). Diabetic patients with diffuse macular edema and diabetics patients with diabetic retinopathy and diffuse macular edema demonstrated improved visual acuity while taking the agents disclosed in Crary. Thus, Crary discloses that there are at least one agent treats diabetic retinopathy and diffuse macular edema in diabetics so the Examiner does not find the unequivocal evidence in the applied art needed to support the fact pattern and conclusion set forth by Applicant as supported by the 'common knowledge' and maintains the applied rejections.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW